THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DAVID DEARINGER and GANNA DEARINGER,

Plaintiff,

v.

ELI LILLY AND COMPANY ,

Defendants.

CASE NO. C21-0060-JCC

ORDER

This matter comes before the Court on Defendant Eli Lilly and Company's motion to dismiss for failure to state a claim (Dkt. No. 14). Having thoroughly considered the briefing and the relevant record, the Court hereby GRANTS Defendant's motion (Dkt. No. 14) and DISMISSES Plaintiffs' complaint without prejudice for the reasons explained below.

I. BACKGROUND

Plaintiffs allege that in 2018, Mr. Dearinger suffered an intracerebral hemorrhage leading to a paralytic stroke within two hours of taking Cialis, a prescription drug that Defendant manufactured and sold. (Dkt. No. 10 at 4.) Cialis is used to treat erectile dysfunction, enlarged prostate symptoms, and pulmonary arterial hypertension. (*Id.*) Plaintiffs claim that, as a result of this stroke, Mr. Dearinger suffered permanent loss of sensory and motor function of the left side

of his body. (*Id.*) They assert five causes of action under Washington's Products Liability Act, (Chapter 7.72 RCW): (1) design defect; (2) failure to warn at the time of manufacture; (3) failure to warn after manufacturing; (4) breach of warranty; and (5) loss of consortium. (Dkt. No. 10 at 7–11.) Plaintiffs allege Defendant knew or should have known Cialis presented a risk of paralytic stroke and failed to adequately warn of this risk. (*Id.* at 7–10.) Plaintiffs claim that Cialis's label does not adequately warn of the risk of *cerebro*vascular events because it warns of the risk of stroke only in the context of "cardiovascular events." (Dkt. No. 32 at 5.)

In April 2021, Defendant filed a motion to dismiss for failure to state a claim. (Dkt. No. 14 at 9). It argued, among other things, that under the learned intermediary doctrine, any duty to warn was owed only to Mr. Dearinger's prescribing physician, such that adequately pleading the claim requires alleging that the doctor would have taken a "different course of action" had Defendant provided a different warning. (*Id.*) Plaintiffs responded urging the Court to adopt an exception to this doctrine for prescription drugs marketed directly to consumers, (Dkt. No. 25 at 12), and the Court certified the question to the Washington State Supreme Court. (Dkt. No. 28.) The Supreme Court declined to recognize this exception and held that the learned intermediary doctrine applies to prescription drugs marketed directly to consumers. (Dkt. No. 30-1 at 19.) The parties then each submitted additional briefs (Dkt. Nos. 32, 34).

II. DISCUSSION

A. Legal Standard

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id*. The Court accepts as true all material allegations of fact and construes the complaint in a light "most favorable to the non-moving party," however merely

"conclusory allegations of law and unwarranted inferences" will not defeat an otherwise proper Rule 12(b)(6) motion. *See Vasquez v. L.A. Cty.*, 487 F.3d 1246, 1249 (9th Cir. 2007) (internal citation omitted).

The Court "ha[s] an obligation to give a liberal construction to the filings of *pro se* litigants." *Blaisdell v. Frappiea*, 729 F.3d 1237, 1241 (9th Cir. 2013). The Court will thus hold Plaintiffs' filings "to less stringent standards than normal pleadings drafted by lawyers." *Hughes v. Rowe*, 449 U.S. 5, 9 (1980) (internal quotation marks omitted).

B. Plaintiffs' Failure-to-Warn Claims (Dkt. No. 10 at 7–8)

The Court cannot determine at this stage whether the warning provided by Defendant as to the risk of cerebrovascular stroke was legally adequate. *See Montalbano v. Ariad Pharm., Inc.*, 2015 WL 11198245, slip op. at 6 (S.D. Fla. 2015) (determining adequacy of the warning was not well-advised at 12(b)(6) stage and better suited for summary judgement or trial); *Webb v. Stryker Corp.*, 2016 WL 11783344, slip op. at 3 (W.D. Pa. 2016) (plaintiffs need not allege, at the pleadings stage, precisely how a warning was deficient or how an adequate warning would have prevented injury). This is generally a question of fact for the jury and only becomes a question of law where the warning is "accurate, clear, and unambiguous." *Ludy v. Eli Lilly and Company*, 2020 WL 3510811 slip op. at 4 (S.D. Ind. 2020) (internal quotation marks omitted). In this case, there is sufficient ambiguity in Cialis's label and about whether a more specific stroke warning was needed to prevent the Court from deciding the issue at the pleadings stage.

Plaintiffs' claim, however, is still inadequately pled, as they fail to allege whether a different label would have affected the prescribing physician's decision to prescribe Cialis to Mr. Dearinger. A failure to warn claim requires a plaintiff to show that (1) the defendant failed to adequately warn, (2) the plaintiff suffered damages, and (3) the defendant's failure to warn proximately caused the plaintiff's damages. *Breen v. Ethicon, Inc.*, 2021 WL 673485 slip op. at 5 (W.D. Wash. 2021). But under the learned intermediary doctrine, a pharmaceutical manufacturer satisfies its duty to warn the *patient* by properly warning the prescribing *physician* of the risks of

its product. *Dearinger v. Eli Lilly & Co.*, 510 P.3d 326, 329 (Wash. 2022). The Washington State Supreme Court confirmed that this principle applies even when a drug manufacturer advertises its product directly to consumers. *Id.* at 331–33. Thus, to establish proximate cause, plaintiffs must allege that a different warning would have impacted the *physician's* decision to prescribe this medication. *See Tutwiler v. Sandoz, Inc.*, 726 F. App'x 753, 756 (11th Cir. 2018) (finding allegations insufficient as plaintiff failed to allege that her physician would not have prescribed the drug if he had been aware of the risks).

Even accepting Plaintiffs' allegations that Cialis contained an inadequate warning about the risk of suffering a particular type of stroke, they still have failed to allege that the prescribing physician would have acted differently had Defendant provided an adequate warning. *Id.* The Court believes that Plaintiffs can cure this defect by amending their complaint to properly allege proximate cause of Mr. Dearinger's injuries within the framework of the learned intermediary doctrine.

C. Preemption (Dkt. No. 14 at 10)

Defendant claims that Plaintiffs' design defect claim is preempted because federal law forbids Defendant from changing Cialis's label design without prior FDA approval. (Dkt. No. 14 at 11). Manufacturers, however, *can* change their warning label without FDA approval by proposing a "changes being effected" ("CBE") labeling change, which underscores the "central premise of federal drug regulation that a manufacturer bears responsibility for the content of its label at all times." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010). Defendant could raise an affirmative defense by showing "by clear evidence" that the FDA would have rejected this label change. *See id.* at 396 (holding plaintiff's claims were not preempted where defendants failed to show by clear evidence the FDA would have rejected a label warning change). But because such a claim requires evidence, it fails at the pleadings stage and is more appropriate for summary judgment.

Moreover, the FDA's statutory scheme governing approval for drugs does not evidence congressional intent to insulate drug manufacturers from liability or otherwise alter state

products liability law. *See Laisure-Radke v. Par Pharm., Inc.*, 2006 WL 901657 slip op. at 5–6 (W.D. Wash. 2006) (finding no conflict between state and federal laws); *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (ruling that defendant's preemption claim was an "untenable interpretation of congressional intent" and an "overbroad view" of agency's power to preempt state law).

While it is true that *generic* drug manufacturers cannot unilaterally change their labels (because they must match the brand-name labels), Cialis is the brand name of the generic drug tadalafil, therefore this restriction does not apply to Defendant. (Dkt. No. 14 at 1); *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475–477 ("[F]ederal law prohibits generic drug manufacturers from independently changing their drugs' labels."). Consistent with this, the Court in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 616 (2011) explained that even generic drug makers could propose warning label changes to the FDA if they thought it necessary, and the FDA would "have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug."[1] Indeed, the FDA requires that "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.57(e). Therefore, Plaintiffs' design defect claim is not preempted.

D. Plaintiffs' Warranty Claim (Dkt. No. 10 at 10)

Defendant asserts that Plaintiffs' warranty claim fails because there was no contractual privity between the parties and Plaintiffs fail to allege any express representations were made to sustain an express warranty claim. (Dkt. No. 14 at 14.) Plaintiffs' opposition briefs do not address their warranty claims at all. (*See generally* Dkt. Nos. 23, 25, 32.)

To establish a breach-of-warranty claim, the plaintiff must be in contractual privity with the defendant. *Baughn v. Honda Motor Co., Ltd.*, 727 P.2d 127, 151–152 (Wash. 1986). Here, Plaintiffs fail to allege contractual privity with Defendant because they do not assert that they purchased Cialis directly from Defendant. (*See generally* Dkt. No. 10.) The privity requirement

[1] The Court nonetheless applied preemption in *PLIVA* for reasons that are not relevant here.

can be relaxed when a manufacturer makes express representations about the product. *Baughn*, 727 P.2d at 152. Under the learned intermediary doctrine, however, the express warranties run to the physician rather than the plaintiff. *Tapia v. Davol, Inc.*, 116 F.Supp.3d 1149, 1162 (S.D. Cal. 2015) (finding plaintiff failed to allege their prescribing physician read and relied on express warranties made about the product). Therefore, Plaintiffs' express warranty claim fails even in the absence of the privity requirement as they fail to allege that Mr. Dearinger's physician relied on express representations about Cialis. (*See generally* Dkt. No. 10.)

E. Loss of Consortium

As Plaintiffs' predicate causes of action are dismissed, their loss-of-consortium claim also fails, as such claims cannot independently stand. *See Carter v. Ethicon Inc.*, 2021 WL 1893749 slip op. at 3 (W.D. Wash. 2021) (dismissing loss-of-consortium claim because all of plaintiff's statutory claims were dismissed).

III. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss (Dkt. No. 14) is GRANTED; and Plaintiffs' claim is DISMISSED without prejudice and with leave to amend. Plaintiffs shall file an amended complaint addressing the deficiencies noted above within 30 days of this order. Failure to do so may result in the dismissal being converted to a dismissal with prejudice, without notice to Plaintiffs.

DATED this 30th day of June 2022.

John C. Coughenour
UNITED STATES DISTRICT JUDGE